

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION

THIS DOCUMENT RELATES TO:

TRACK THREE

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

**CVS'S SUBMISSION REGARDING THE COURT'S
FINAL DRAFT JURY INSTRUCTIONS**

Pursuant to the Court's directive on the morning of November 2, 2021, CVS makes this submission regarding the final draft jury instructions that Special Master Cohen circulated to the parties on November 1, 2021. As discussed with the Court, CVS makes this submission to address certain instructions. CVS preserves, and does not waive, its objections to other instructions. As discussed with the Court, CVS will make a more complete submission, at a later date, to fully state and preserve its objections to the jury instructions.

I. Objections to Draft Instructions

A. Unlawful Dispensing Conduct – Pharmacists

CVS objects to the draft instruction on unlawful dispensing conduct by a pharmacist (page 24). The instruction states that “the pharmacist has a corresponding responsibility *to ensure* the prescription is dispensed for a legitimate medical purpose.” (Emphasis added). It deviates from the plain language of the corresponding responsibility regulation and disregards the mens rea requirement set forth therein. That regulation, 26 C.F.R. § 1306.04(a), provides that a pharmacist fails to exercise corresponding responsibility only when she “knowingly” fills a prescription that

was not written for a legitimate medical purpose.¹ The preamble to the regulation expressly states that the word “knowingly” was added to the regulation “to require knowledge” of illegitimacy in order to avoid placing an obligation on the pharmacist to ensure the legitimacy of each prescription. Ex. A, Department of Justice, Bureau of Narcotics and Dangerous Drugs, “Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970, 36 Fed. Reg. 80, 7777 (Apr. 24, 1971).² By disregarding the knowledge requirement and instructing jurors that a pharmacist has an obligation “to ensure” the legitimacy of a prescription, this instruction runs afoul of the plain language and clear intent of the corresponding responsibility regulation.

CVS therefore proposes the following edits to the “Unlawful Conduct – Dispensing” instruction on page 24:

Under both Federal and Ohio laws and regulations, entities that are authorized to dispense controlled substances are required to provide effective controls and procedures to guard against theft and

¹ The full text of the regulation reads:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person **knowingly** filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04(a) (emphasis added). The applicable Ohio regulation, Ohio Administrative Code 4729-5-21(A), is virtually identical.

² The preamble states: “The National Association of Retail Druggists objected to the responsibility placed upon a pharmacist under § 306.04 to determine the legitimacy of a prescription. ***The language has been revised to require knowledge.***” (Emphasis added.)

diversion. A prescription for a controlled substance must be issued for a legitimate medical purpose by a doctor, or other registered prescriber, acting in the usual course of his or her professional practice. The Federal and Ohio Controlled Substances Acts and their accompanying regulations also provide that **a corresponding responsibility rests with** the pharmacist who fills the prescription ~~has a corresponding responsibility to ensure the prescription is dispensed for a legitimate medical purpose.~~ **A pharmacist fails to exercise corresponding responsibility when she knowingly fills a prescription that was not written for a legitimate medical purpose.** The corresponding responsibility **not to knowingly fill a prescription that was not written for a legitimate medical purpose** ~~ensure the dispensing of valid prescriptions~~ extends to the pharmacy itself.

B. Unlawful Dispensing Conduct – Pharmacies

CVS also objects to the last sentence of the same instruction (page 24). That sentence states that “[t]he corresponding responsibility to ensure the dispensing of valid prescriptions *extends to the pharmacy itself.*” (Emphasis added.) Not only does the instruction ignore the knowledge requirement in the corresponding responsibility regulation, it incorrectly instructs the jury that the legal obligation to exercise corresponding responsibility extends from the pharmacist to the pharmacy despite the absence of any language in the regulation to that effect. The unambiguous language of the regulation states that the corresponding responsibility “rests with the pharmacist who fills the prescription” without any mention whatsoever of the pharmacy. Accordingly, CVS proposes the following additional edit to the “Unlawful Conduct – Dispensing” instruction on page 24, striking the last sentence:

Under both Federal and Ohio laws and regulations, entities that are authorized to dispense controlled substances are required to provide effective controls and procedures to guard against theft and diversion. A prescription for a controlled substance must be issued for a legitimate medical purpose by a doctor, or other registered prescriber, acting in the usual course of his or her professional practice. The Federal and Ohio Controlled Substances Acts and their accompanying regulations also provide that **a corresponding responsibility rests with** the pharmacist who fills the prescription ~~has a corresponding responsibility to ensure the prescription is dispensed for a legitimate medical purpose.~~ **A pharmacist fails to**

~~exercise corresponding responsibility when she knowingly fills a prescription that was not written for a legitimate medical purpose. The corresponding responsibility ensure the dispensing of valid prescriptions extends to the pharmacy itself.~~

CVS recognizes that a pharmacy that employs a pharmacist may be held liable for actions that the pharmacist takes within the scope of her employment. The Court has included elsewhere (on page 18) a draft instruction on respondeat superior. CVS does not object to that instruction.

C. Causation – Substantial Factor

CVS objects to the draft causation instruction regarding “substantial factor” (page 25). The instruction states in part: “Conduct is a substantial factor if it has some material, meaningful, or considerable effect and that effect is not trivial, negligible, remote, or insignificant. A Defendant’s conduct is ‘substantial’ if a reasonable person would regard that conduct as the cause or one of the causes of the nuisance.” Instructing the jury that a defendant’s conduct can be a substantial cause if it was “not trivial, negligible, remote, or insignificant” invites a verdict against a defendant when its conduct was not in fact a substantial cause. In this regard, the language invites a verdict based on a causal effect that is but a hair more than “trivial, negligible, remote, or insignificant.” Including this language would be similar to defining reasonable doubt in a criminal case as more than a preponderance of the evidence. That would obviously be erroneous; it would allow a verdict based on some quantum of proof more than a preponderance of the evidence but less than reasonable doubt.

The prejudice is amplified by instructing the jury that a defendant’s conduct was “substantial” if a reasonable person would consider it to be “one of the causes.” This sentence further reads the “substantial factor” requirement out of the instruction. It further risks juror confusion on what is a substantial cause. Just because a defendant’s conduct was “one of the

causes” does not mean that it was a substantial cause. In fact, a defendant’s conduct can be “one of the causes” even it was a “trivial, negligible, remote, or insignificant” cause.

The “substantial factor” instruction is critical in this case as even plaintiffs’ own experts have testified that non-parties such as drug manufacturers, the FDA, and the DEA caused the “opioid epidemic” or were the “major causes.” Doc. 4064 at 3547:12-14, 3532:23-3533:4, 3588:10-3559:13. It is paramount that the jury have a clear instruction on what is a substantial cause. Accordingly, CVS proposes the following edits to the “substantial factor” instruction:

An individual Defendant’s conduct need not be independently capable, all by itself, of causing the public nuisance. There may be multiple causes of a public nuisance. The fact that some other cause or causes combined with a Defendant’s conduct in creating the public nuisance does not relieve that Defendant from liability if the Plaintiff can prove that the conduct the Defendant engaged in was a **substantial factor** in creating the public nuisance. Conduct is a substantial factor if it has some material, meaningful, or considerable effect ~~and that effect is not trivial, negligible, remote, or insignificant.~~ A Defendant’s conduct is “substantial” if a reasonable person would regard that conduct as the cause or one of the **material, meaningful, or considerable** causes of the nuisance. If you find that the conduct of any Defendant proximately caused a public nuisance, it is not a defense to liability that some other entity may also be to blame.

D. Intentional Conduct

CVS incorporates by references Walmart’s and Walgreens’ objections to the final draft instructions on intentional conduct (pages 19 and 21). Now that it is clear that plaintiffs’ claims are based solely on dispensing conduct that is governed by the Controlled Substances Act and its implementing regulations, the Court should strike the intentional conduct instruction or clarify for the jury that a public nuisance claim cannot be based on intentional conduct that is authorized by a statute, ordinance, or regulation.

II. Proposed Jury Instructions

CVS proposes two additional jury instructions to address certain issues that have arisen during the course of trial.

First, CVS proposes the following instruction to make clear that the issue in this case is whether defendants engaged in unlawful conduct that caused a public nuisance and not whether defendants engaged in negligent conduct:

The question in this case is whether defendants engaged in unlawful conduct that was a substantial factor in causing a significant and ongoing public nuisance. If a defendant did not engage in unlawful conduct, whether the defendant could have done better, could have done more, or could have done something different with respect to the dispensing of prescription opioid medications is not relevant and may not be considered by you. You are to consider only whether a defendant substantially complied with the legal requirements as they have been described to you and, if it has not, whether the defendant's failure to do so was a substantial factor in causing a significant and ongoing public nuisance.

Second, CVS proposes the following instruction on the role of a pharmacist in delivering healthcare to a patient:

Pharmacists are not licensed by the state to practice medicine and therefore may not practice medicine. They also are not registered with the DEA to write prescriptions. If a prescription has a legitimate medical purpose, a pharmacist may not second-guess the medical judgment of the prescriber who wrote it.

III. Reservations of Rights

In making this submission, CVS preserves, and does not waive its objections to the other jury instructions not addressed herein. CVS has stated many of those objections in prior submissions and, as discussed above, will make a subsequent submission setting forth in full its objections to the jury instructions.

Dated: November 5, 2021

Respectfully submitted,

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